Brooklyn Law Review

Volume 75
Issue 2
SYMPOSIUM:
Is Morality Universal, and Should the Law Care?

Article 9

2009

Caffeine: The New "Energy" Crisis: The Dietary Supplement Health and Education Act of 1994 and Its Implications for Caffeine Regulation

Nausheen Rokerya

Caffeine: The New "Energy" Crisis

THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 AND ITS IMPLICATIONS FOR CAFFEINE REGULATION

INTRODUCTION

Caffeine is the "only addictive psychoactive substance that has overcome resistance and disapproval around the world to the extent that it is freely available almost everywhere, unregulated, sold without license, offered over the counter in tablet and capsule form, and even added to beverages intended for children."[1] As a result, while Americans continue to work hard each day, more and more rely on caffeine to fuel their energy needs. Each day, Americans consume 400 million cups of coffee.[2] In particular, coffee consumption among young adults rose to 3.2 cups per day in 2008 from 2.4 cups per day in 2005.[3] The energy drink market displays similar consumption trends. Since the worldwide introduction of Red Bull in 1997,[4] energy drink consumption has continued to dramatically increase, accounting for 2.5 billion dollars in sales in 2005.[5] For those who would rather not wait for liquid caffeine to kick in, caffeine pills such as No Doz contain about 100 to 200mg of caffeine each (roughly equivalent to two cups of coffee) and begin

---

[1] BENNETT ALAN WEINBERG & BONNIE K. BEALER, THE WORLD OF CAFFEINE: THE SCIENCE AND CULTURE OF THE WORLD'S MOST POPULAR DRUG, at xi (2001).

[2] Coffee Statistics Report 2008, http://www.coffee-statistics.com/coffee_statistics_ebook.html (last visited Sept. 29, 2009).

[3] Nat'l Coffee Ass'n of U.S.A., Inc., 2008 National Coffee Drinking Trends Study, *available at* http://www.ncausa.org/i4a/pages/index.cfm?pageID=648 (last visited Sept. 29, 2009).

[4] Red Bull Website, http://www.redbullusa.com/ (follow "Products" hyperlink; then follow "Company" hyperlink; then follow "Worldwide Expansion" hyperlink) (last visited Sept. 29, 2009).

[5] Shane Starling, *Scrutiny Intensifying for Energy Drink Claims*, 64 FUNCTIONAL FOODS & NUTRACEUTICALS 6 (2007), *available at* http://www.functionalingredientsmag.com/article/North-American-Regs/scrutiny-intensifying-for-energy-drink-claims.aspx.

working in the body quickly and all at once.[6] Whether used to start one's day, or simply get through it, caffeinated substances have developed "a certain contemporary cachet in American society."[7] Despite the surging popularity of caffeine products, they can be easily and unintentionally abused. This abuse is responsible for many societal ills, including increased rates of miscarriage,[8] "driving under intoxication" ("DUI") charges,[9] caffeine poisoning in children and teens,[10] and several other health complications[11] for misguided consumers.

Part of the reason for this abuse of caffeine is that the Food and Drug Administration (FDA) has not adequately addressed it. Because caffeine is found in "such a wide variety of products, it poses interesting regulatory challenges for the FDA."[12] As a result, regulation of caffeine has been

---

[6] Emily Martin, *Caffeine Pills Can be Fatal if Abused*, CAPITAL, Apr. 30, 2007 at C1.

[7] David M. Mrazik, Reconsidering Caffeine: An Awake and Alert New Look at America's Most Commonly Consumed Drug 3 (2004) (unpublished manuscript, *available at* http://leda.law.harvard.edu/leda/data/642/Mrazik.pdf).

[8] Jacqui Wise, *High Coffee Intake Increases Risk of Miscarriage*, 319 BRIT. MED. J. 1456, 1456 (1999). This correlation is observed even for those women who consume moderate amounts of caffeine during their pregnancies. *Miscarriage Risk Increases With High Caffeine Consumption*, 22 NURSING STANDARD 16, 16-17 (2008) ("women who consumed up to 200mg of caffeine a day had an increased risk of miscarriage (15 per cent versus 12 per cent.)")

[9] *See generally*, Mary Claire O'Brien et al., *Caffeinated Cocktails: Energy Drink Consumption, High-risk Drinking, and Alcohol-related Consequences among College Students*, 15 ACAD. EMERGENCY MED. 453, (2008) [hereinafter Cocktails]; Press Release, Ctr. for Sci. in the Pub. Interest, CSPI Sues to Stop MillerCoors' "Sparks" Alcoholic Energy Drink: Caffeinated Booze Linked to Binge Drinking, Drunk Driving, and Assaults (Sept. 8, 2008); Letter from Stephen Gardner to Tom Long (Feb. 28, 2008), *available at* http://www.cspinet.org/new/pdf/cspimiller.pdf.

[10] Christine A. Haller et al., *Dietary Supplement Adverse Events: Report of a One-Year Poison Center Surveillance Project*, 4 J. MED. TOXICOLOGY 84, 86 (2008); *see also* TheBostonChannel.com, *Caffeine Behind 4,600 Calls to Poison Control*, *available at* http://www.thebostonchannel.com/news/16844829/detail.html (last visited Sept. 29, 2009).

[11] According to the Food and Drug Administration, caffeine may lead to a number of physical responses, including jitters, insomnia, rapid heart beat, uneven heart rhythm, elevated blood pressure, headaches, nervousness, dizziness, and dehydration. FDA AND YOU, MEDICINES IN MY HOME: CAFFEINE AND YOUR BODY (2007), http://www.fda.gov/cdrh/fdaandyou/issue14.html#5; [hereinafter FDA AND YOU] (last visited Jan. 7, 2009); *see also* C.J. Reissig et al., *Caffeinated Energy Drinks—A Growing Problem*, 99 DRUG & ALCOHOL DEPENDENCE 1, 5 (2009). Other research has suggested links between caffeine consumption and increased risk of heart disease. *See* Andrea Z. LaCroix et al., *Coffee Consumption and the Incidence of Coronary Heart Disease*, 315 NEW ENG. J. MED. 977, 977-82 (1986).

[12] Mrazik, *supra* note 7, at 24.

inconsistent.[13] Today, the FDA does not possess adequate statutory authority to address this inconsistency.[14] The FDA does not uniformly require caffeinated products to contain warning labels about the possible health risks of caffeine consumption.[15] Further, even where the FDA does require a warning label, it does not require that this warning label disclose the caffeine content of the substance.[16] This is problematic, since the FDA's limits on the amount of caffeine a substance may contain are also inconsistent.[17] For example, while the FDA does generally limit the amount of caffeine that can be added to soft drinks,[18] many manufacturers of other caffeine-containing substances escape these limits by claiming that their products fall under the 1994 Dietary Supplement Health and Education Act (DSHEA).[19] DSHEA classifies herbal products and products derived from natural sources as "dietary supplements," rather than drugs,[20] placing them in a less-regulated category of substances. This system of dual regulation is based on an interpretation of the Food Drug and Cosmetic Act,[21] which provides for FDA regulation of substances that appear both in foods and drugs, based on how the product is advertised.[22] Not surprisingly, this significant marketing flexibility makes dietary supplements one of the

---

[13] *See generally* Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Regulation in the United States*, 27 CUMB. L. REV. 65 (1997) (discussing the history of caffeine regulation and its implications).

[14] *Id*. at 83-85. (explaining that while the FDA requires OTC caffeine pills to contain warning labels, other caffeinated substances containing greater amounts of caffeine, such as some energy drinks, are not required to display any labeling).

[15] *Id.* at 80.

[16] *Id.*

[17] *Id.* at 84.

[18] "Soda" beverages may not contain more than approximately 70mg of caffeine per 12 fluid ounces, (.02 per cent). 21 C.F.R. § 182.1180 (2009).

[19] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.).

[20] 21 U.S.C. § 3(a) (2006); *see also* Reissig et al., *supra* note 11, at 1 (discussing the implications of DSHEA for caffeine regulation).

[21] 21 U.S.C. §§ 301-399a.

[22] Prothro, *supra* note 13, at 76-77 ("Thus, if one markets a caffeinated soft drink as just a soft drink, it will likely be regulated as a food. But if one markets it as a soft drink to help maintain 'blood energy, muscular activity, sound teeth and gums,' it will likely be regulated as a drug and require FDA pre-market approval." (footnote omitted)); *see also* Mrazik, *supra* note 7, at 24 ("If it is sold to be used both as a food and for the prevention or treatment of disease it would satisfy both definitions and be subject to the substantive requirements for both." (internal quotation marks omitted) (quoting S. Rep. No. 74-361, at 4 n.39 (1935))).

fastest growing segments of FDA-regulated products.[23] Finally, even where caffeine regulations do apply, the FDA has failed to enforce them.[24]

The caffeine industry is dynamic, both fueling and satisfying rapidly changing consumer needs. Coffee houses are diversifying drinks' sizes, strengths, and flavors to appeal to a wider array of coffee drinkers. Energy drink manufacturers often engage in targeted advertising,[25] allowing them to appeal to younger and more uninformed consumer bases. Caffeinated pills, gums, and even soaps are infiltrating college campuses to answer the weary call of the sluggish student.[26] While moderate consumption may not be problematic, increasing awareness among the American population about what moderation entails is a timely issue that must be addressed in order to prevent future generations from suffering the consequences of caffeine abuse and unintentional overconsumption.

Part I of this note discusses current caffeine usage trends and the various public health concerns surrounding caffeine consumption. Part II then outlines the history of the government's approach to caffeine regulation and examines the inadequacies of the current regulatory framework for all caffeinated substances. This Part highlights the glaring inconsistencies that have contributed to the overarching issue of inadequate consumer awareness, and discusses the resulting vulnerabilities of both the public at large, and manufacturers of caffeine-containing products. Part III proposes a two-pronged approach to comprehensively address the under-regulation and over-consumption of caffeine. The first prong consists of several changes in the existing regulatory framework regarding caffeine. While comprehensive regulation is much needed, this shift alone will not be sufficient to address the problem. Therefore, a second prong composed of a "soft-paternalism" educational awareness campaign is needed, which would encourage well-informed decision-making on the part of consumers.

---

[23] Reissig et al., *supra* note 11, at 1 (discussing recent trends in the energy drink market).

[24] *Id.* at 2.

[25] *See infra* footnotes 60-68 and accompanying text.

[26] *See generally* Caffeine Candy, Caffeine Pills/Tablets, and Even Caffeine Soap!, http://www.xoxide.com/caffeine-candy.html (last visited Oct. 30, 2009).

I. CAFFEINE

A. Caffeine in America: A Nation of Caffeine Addicts

Caffeine is an ever-increasing presence in the lives of Americans, as it is found in products as diverse as coffee, tea, cola beverages, energy drinks, chocolate, and medicines. While some doctors recommend that one's daily intake of caffeine should not exceed 200mg,[27] the average person in the United States consumes about 280mg of caffeine per day.[28] Since most caffeinated products do not contain quantitative content labeling,[29] many unsuspecting consumers may unknowingly ingest caffeine in amounts far in excess of the recommended limit. The result is that many Americans subject themselves to a myriad of complications from caffeine over-consumption.

This note examines three major sources of caffeine in the United States: coffee, caffeine pills, and energy drinks. Coffee has long been America's favorite. By the mid-nineteenth century, "America was consuming more coffee than any country in the world."[30] Today, in the United States, seventy-five percent of caffeine is consumed in the form of coffee.[31] According to the FDA, a five- ounce cup of coffee may contain anywhere from 60 to 150mg of caffeine.[32] However, this statistic may be misleading, since many consumers purchase larger cup sizes. A 16-ounce cup of coffee from McDonalds and Dunkin Donuts each contain 145mg and 143mg of caffeine respectively.[33] The same 16-ounce cup from Starbucks, (which controlled seventy-three percent of the U.S. coffee market-share in 2006),[34] contains a whopping 330mg of caffeine.[35]

---

[27] FDA AND YOU, *supra* note 11, at 4-5.

[28] Laura M. Juliano & Roland R. Griffiths, *A Critical Review of Caffeine Withdrawal: Empirical Validation of Symptoms and Signs, Incidence, Severity, and Associated Features*, 176 PSYCHOPHARMACOLOGY 1, 1 (2004).

[29] *See supra* notes 15-16 and accompanying text.

[30] WEINBERG & BEALER, *supra* note 1, at 185.

[31] Coffee Statistics Report 2008, *supra* note 2.

[32] FDA AND YOU, *supra* note 11 (amount of caffeine in a cup of coffee may vary with the type of coffee, the way in which it was brewed, and the amount of time it was brewed).

[33] Energy Fiend, Caffeine Content of Drinks, http://www.energyfiend.com /the-caffeine-database [hereinafter Energy Fiend] (last visited Sept. 29, 2009).

[34] Edward Iwata, *Owner of Small Coffee Shop Takes on Java Titan Starbucks*, USA TODAY, Dec. 20, 2006.

[35] Pike Place Roast Beverage Details, http://www.starbucks.com/retail/nutrition_beverage_detail.asp?selProducts={EA82FB82-E455-40BD-A404-87EE7345EB7F}&x=24&y=3&strAction=GETDEFAULT. (last visited Oct. 10, 2009).

Furthermore, because over 100mg of caffeine can cause physical dependency,[36] it is easy to become addicted to caffeine from a daily cup of coffee, prompting consumers to buy even more coffee, or seek out the one with the highest caffeine content to boost its effect. For example, if a customer drinks a large coffee from Starbucks on Monday and Tuesday mornings, but switches to Dunkin Donuts on Wednesday, she will not likely experience the same desired effect and may experience withdrawal symptoms. Some brands have created products specifically for this niche of caffeine seekers. For example, Spike Coffee, whose trademark is "The Coffee for Caffeine Addicts"[37] advertises itself as containing over fifty percent more caffeine than others.[38]

Coffee also serves a social function. People often congregate at coffee shops for dates, meetings, or other social gatherings. As one researcher notes, "[c]offee is a drink that is now part of the culture . . . we have a social code around its consumption. We linger over it during lunch with friends, serving sizes are standardized, and its use is integrated into our everyday behavior."[39] Furthermore, one of "the most noteworthy feature[s] of American cafés . . . [is that] . . . '[t]hey refill your cup without charge, even without asking.'"[40] This aspect of coffee culture is unique to America—many European coffee houses charge twice as much as American coffee houses for a much smaller cup, and do not offer free refills.[41]

Although many people get their caffeine from coffee, more and more Americans turn to over-the-counter caffeine pills when a morning 'cuppa joe' doesn't suffice.[42] A single dosage of pills such as No Doz, or Vivarin contains approximately 200mg of caffeine.[43] Since caffeine is the only

---

[36] Posting of William W. Peters to masslive.com, http://blog.masslive.com/pioneerparent/2008/04/the_buzz_on_energy_drinks.html (Apr. 23, 2008, 15:35 EST) [hereinafter Peters].

[37] WEINBERG & BEALER, *supra* note 1, at 204.

[38] *Id.*

[39] Terri Coles, *Caffeinated Boosters May Have Down Side for Teens*, TORONTO, Oct. 3, 2008, *available at* http://www.qualityhealth.com/news/caffeinated-boosters-may-down-side-teens-11073. (last visited Oct. 10, 2009).

[40] WEINBERG & BEALER, *supra* note 1, at 185 (quoting a European visitor's opinion of American cafes).

[41] *Id.*

[42] *See* Tracy Jan, *Colleges Calling Sleep a Success Prerequisite*, BOSTON GLOBE, Sept. 30, 2008, at A1 (describing various methods that college students use to maintain their energy levels during the strenuous academic year).

[43] Ctr. For Sci. in the Pub. Interest, *Caffeine Content of Food & Drugs* (Sept. 2007), http.www.cspinet.org/new/cafchart.htm [hereinafter CSPI Caffeine Contents].

"alertness aid" approved for sale by the FDA, manufacturers of caffeine pills are in the "position of being the legal producers and sellers of one of the only over-the-counter psychoactive stimulant drugs outside the matrix of a food or beverage."[44] One of the biggest marketing problems faced by these producers is how to promote sales (consumption) without seeming to encourage underage use of caffeine or abuse by adults.[45] One method, adopted by No Doz, involves advertising itself as being as "safe as coffee."[46]

In addition to pills marketed for increasing alertness, other common medications also contain caffeine. Caffeine is frequently added to a number of other over-the-counter drugs that are primarily aimed at treating ailments such as migraines or menstrual cramps.[47]

Energy drinks constitute a third source of caffeine. The energy drinks industry is one of the fastest growing business segments in the United States. In 2006, this market was worth $5.4 billion,[48] which represented approximately a fifty percent increase per year over the previous five years.[49] A recent survey revealed that fifty-one percent of college students consumed at least one energy drink per month.[50]

Because of this increasing demand for energy drinks, the industry has expanded and there are now several different types of energy drinks available to the public. In their effort to attract attention in a market dominated by pioneer Red Bull, manufacturers of energy drinks compete on the basis of highest caffeine content.[51] Thus, Red Bull, which is sold in an 8.3-ounce

---

[44] WEINBERG & BEALER, *supra* note 1, at 195.

[45] *Id.*

[46] *See* Image of No Doz Pill Box, http://pics.drugstore.com/prodimg/15870/200.jpg (last visited Sept. 29, 2009).

[47] Midol contains 120mg of caffeine per two-tablet dosage. *See Midol Frequently Asked Questions*, http://www.midol.com/faqs.html (last visited Sept. 29, 2009). Excedrin (Extra Strength) contains 130mg of caffeine per two-tablet dosage. CSPI Caffeine Contents, *supra* note 43. Anacin (Maximum Strength) contains 64mg of caffeine per two-tablet dosage. *Id.*

[48] Coles, *supra* note 39.

[49] *Id.*

[50] "Fifty one percent of participants . . . reported consuming greater than one energy drink each month in an average month for the current semester . . . . Using energy drinks is a popular practice among college students for a variety of situations." Brenda M. Malinauskas et al., *A Survey of Energy Drink Consumption Patterns Among College Students*, 6 NUTR. J. 35 (2007), *available at* http://www.nutritionj.com/content/pdf/1475-2891-6-35.pdf.

[51] Thomas J. Boud, *The Energy Drink Epidemic*, ENSIGN, Dec 2008., at 48-52, *available at* http://www.lds.org/ldsorg/v/index.jsp?hideNav=1&locale=0&sourceId=

can, contains 80mg of caffeine.[52] Monster (promoted by its manufacturer as "a wicked mega hit that delivers twice the buzz"[53]) and Rock Star energy drinks both come in 16-ounce cans with 160mg of caffeine.[54] Cocaine, an energy drink touted for its five-hour buzz,[55] was pulled from the market by the FDA last year for its "provocative narcotic-linked moniker and marketing," rather than its whopping 280mg of caffeine.[56] Raising the bar even further, products like Fixx, Wired, and BooKoo Energy have dramatically higher caffeine content[57] ranging from 300mg to 500mg per can.[58] These drinks, like most others on the market, contain caffeine in amounts far above the FDA limit for carbonated cola beverages.[59] Even more alarming, energy drink advertising campaigns are regularly targeted at younger audiences, making these high caffeine content figures particularly concerning.

The overuse of caffeine has become an important part of youth culture.[60] Roughly one-third of twelve to twenty-four-year-olds report "regular" consumption of energy drinks.[61] This trend can be attributed to the fact that energy drink manufacturers arguably market their products to students

---

30952f9318fcd110VgnVCM100000176f620a____&vgnextoid=2354fccf2b7db010VgnVCM1000004d82620aRCRD (last visited Oct. 30, 2009).

[52] CSPI Caffeine Contents, *supra* note 43.

[53] Monster Energy Drink, http://www.monsterenergy.com/product/energy.php (last visited Sept. 29, 2009).

[54] CSPI Caffeine Contents, *supra* note 43.

[55] Melissa Sowry, *The Ultimate Energy Drink: Cocaine?*, ABCNEWS.COM, Sept. 18, 2006, http://abcnews.go.com/Health/story?id=2459718, (last visited Oct. 10, 2009).

[56] *Calm Crucial for Energy Products*, FOODNAVIGATOR.COM, Mar. 25, 2008, http://www.foodnavigator.com/Financial-Industry/Calm-crucial-for-energy-products (last visited Oct. 10, 2009).

[57] Experts Petition FDA to Increase Energy Drink Regulations, ABOUTLAWSUITS.COM, Oct. 22, 2008, http://www.aboutlawsuits.com/experts-petition-fda-for-energy-drink-regulations-1465/ [hereinafter Petition].

[58] Energy Fiend, *supra* note 33; *see also* Petition, *supra* note 57.

[59] *See supra* note 18 and accompanying text (discussing current limits on caffeine content of some carbonated beverages).

[60] "[Y]outh culture . . . thrive[s] on the excessive use of caffeine." BARBARA C. BIGELOW & KATHLEEN J. EDGAR, UXL ENCYCLOPEDIA OF DRUGS & ADDICTIVE SUBSTANCES, VOL. 2: CAFFEINE TO DIURETICS 141 (Thomson Gale 2006).

[61] MICHELE SIMON & JAMES MOSHER, MARIN INSTITUTE, ALCOHOL, ENERGY DRINKS, AND YOUTH: A DANGEROUS MIX 1 (2007), http://www.marininstitute.org/alcopops/resources/EnergyDrinkReport.pdf [hereinafter MARIN INSTITUTE REPORT].

looking to get through that 8:00 a.m. lecture,[62] or athletes looking to gain that extra "edge" in competition.[63]

A recent report from the Marin Institute[64] sums up the tactics used by the energy drink industry to give its products added appeal to younger markets:

> Nonalcoholic energy drink producers promote youth consumption using "grassroots" level marketing strategies, as opposed to traditional channels (such as television, radio, magazine, and outdoor advertising). Companies are looking for "one-on-one relationships" gained through events, extreme sports sponsorships, Internet interactions, text messaging, and communication among users on Internet sites such as My Space and Facebook.[65]

These grassroots marketing approaches are reflected on many energy drinks' websites. For example, Red Bull's official website features clickable categories including "sports," "motorsports," "culture," and "mediamix."[66] Rockstar's website displays pictures of various music artists, and sponsored concerts full of performances by modern punk bands.[67] Its homepage bears the slogan, "Party Like A Rockstar."[68]

With their busy schedules and increasingly demanding workloads, teens and young adults represent an easy target. As one Iowa State student said, while "[our] parents turned to coffee and the occasional soda for their energy needs, students today rely on caffeine in pill form and energy drinks for late-night cram sessions. In fact, many college students feel inadequate without their daily dosage."[69] Companies such as Red Bull have pounced on this vulnerability and seek to increase consumption and brand awareness on college campuses by hiring students to promote their products at these

---

[62] Ann Grey, *Caffeine Takes New Forms*, IOWA STATE DAILY, Feb. 12, 2007, *available at* http://www.iowastatedaily.com/articles/2007/02/12/fyi/20070212-archive.txt.

[63] *See* WEINBERG & BEALER, *supra* note 1, at 287 (discussing "Caffeine and Exercise and Athletic Performance"); *see also* Jenny Deam, *Contrary to Ads, Caffeine Won't Give Athletes an Edge*, DENV. ROCKY MOUNTAIN NEWS, June 29, 1999, at 6D.

[64] MARIN INSTITUTE REPORT, *supra* note 61.

[65] *Id.* at 1.

[66] Red Bull Website, http://www.redbullusa.com/#page=HomePage.1201744549410-1861037906.1 (last visited Jan. 9, 2009).

[67] Rockstar Energy Drink: Photo Galleries, http://www.rockstar69.com/product.php?pdt=9 (last visited Sept. 23, 2009).

[68] *Id.*

[69] Grey, *supra* note 62. *See generally* Sarah Viren, *A Need for Caffeine*, HOUSTON CHRONICLE, Oct. 12, 2005, at A1.

schools,[70] installing machines on campuses,[71] hosting free giveaways,[72] and even coordinating contests where students use cans of Red Bull to create works of art.[73] SmithKline Beecham Inc., manufacturer of the caffeine pill brand Vivarin, launched two web-based promotional programs targeted toward students. "The . . . 'Vivarin Date-Ability Index' [was] intended to be a lighthearted way of asking students to submit personal information in exchange for a humorous report on their social skills."[74] The other campaign involved a competition for students to design the best homepage for Vivarin's website, with the winner receiving a $10,000 scholarship.[75]

One university is currently attempting to take advantage of this dynamic by investing in advertisements for the relatively high-caffeine[76] soft drink Mountain Dew.[77] In an effort to recruit high school students, the University of Wisconsin-Platteville sponsored promotional ads on the cans that contain the university's website.[78]

The introduction of Starbuck's DoubleShot, containing 130mg of caffeine, was specifically targeted toward a younger consumer base[79] of "intensity seekers."[80] The DoubleShot, a

---

[70] Jessica Sidman, *On Campus, Companies Look to Students to Hawk Latest Goods*, DAILY PENNSYLVANIAN, Nov. 20, 2007, at 1, *available at* http://media.www.dailypennsylvanian.com/media/storage/paper882/news/2007/11/20/News/On.Campus.Companies.Look.To.Students.To.Hawk.Latest.Goods-3112094.shtml (last visited Sept. 21, 2009).

[71] Daniella Zalcman, *Red Bull Takes Flight Across Campus*, COLUMBIA SPECTATOR ONLINE EDITION, Nov. 30, 2005, *available at* http://www.www.columbiaspectator.com/2005/11/30/red-bull-takes-flight-across-campus (last visited Sept. 21, 2008).

[72] Penn State Live, Photo album, http://live.psu.edu/album/1619 (discussing Red Bull giveaway at Penn State University event.).

[73] Katherine Levan, *Red Bull Pursues On-Campus Promotions, Seeks to End Mystery*, TUFTS DAILY, Nov. 18, 2004, *available at* http://www.tuftsdaily.com/2.5511/1.598973 (last visited January 9, 2009).

[74] *Vivarin Targets Students With New Promotions*, PHILLIPS MEDIA GROUP'S INTERACTIVE MARKETING NEWS, Oct. 27, 1995, at 1.

[75] *Id.*

[76] Mountain Dew contains 54mg of caffeine/per 12 fluid ounces, compared to Pepsi, which contains 38mg. CSPI Caffeine Contents, *supra* note 43.

[77] UW-P invests in caffeine-fueled ads, TELEGRAPH- HERALD, Dec. 13, 2004, at A3.

[78] *Id.*

[79] Keith Reimer is the former general manager of the North American Coffee Partnership between Pepsi and Starbucks. He is now the president and CEO of Pepsi Bottling Ventures. *See* Keith Reimer—Management Team—About PBV—Pepsi Bottling Ventures, http://www.pepsibottlingventures.com/about/reimer.html (last visited Oct. 10, 2009).

collaboration between Pepsi and Starbucks, comes in a 6.5-ounce can containing two shots of espresso, and resembles an energy drink. This resemblance allows the companies to tap into the rapport that the energy drink industry has already created with younger energy product consumers.[81]

However, young adults are not the only ones being targeted. The effect of such marketing techniques appears to be trickling down to younger children as well. According to one study, average daily caffeine consumption by twelve-to-fourteen year olds amounted to approximately 63mg.[82] This number increases as children enter the teenage years,[83] which can result in undesirable physical effects. One public school official reported that eight to ten students per week visited his district's middle and high schools' nurses' offices as a result of having used high-energy products.[84]

The energy drink industry also targets athletes with its appeals. Monster Energy Drink's website contains a social networking-style[85] section devoted to athletes,[86] where athletes who support the product can sign up and create profiles for others to view.[87] Liquid Lightning Energy Drink's website displays multiple photos of motorbike races, snowmobiles, and young girls clad in cheerleader-type outfits.[88] Mountain Dew's Amp Energy drink includes tabs on its website for "Racing," "Snowboarding," and "BMX."[89]

---

[80] Greg W. Prince, *Pepsi Espressos Itself DOUBLESHOT OF STARBUCKS' LOVE*, BEVERAGE WORLD, Mar. 15, 2002, *available at* AllBusiness.com, http://www.allbusiness.com/retail-trade/eating-drinking-places-eating/4129430.html.

[81] *See* Carolyn Wyman, *Trendy Iced Coffees Appeal to the Young*, PITTSBURGH POST-GAZETTE, July 18, 2002, at X6; *see also* Prince, *supra* note 80..

[82] Charles P. Pollak & David Bright, *Caffeine Consumption and Weekly Sleep Patterns in US Seventh-, Eighth- and Ninth-Graders*, 111 PEDIATRICS 42, 42 (2003).

[83] *See generally* Joel V. Oberstar et al., *Caffeine Use and Dependence in Adolescents: One-Year Follow-up*, 12 J. CHILD ADOLESCENT PSYCHOPHARMACOLOGY 127 (2002).

[84] Peters, *supra* note 36.

[85] Some examples of this style include "myspace.com," or "facebook.com," two popular social-networking sites.

[86] Monster Energy Athlete Page, http://www.monsterenergy.com/web/athletes (last visited Oct. 30, 2009).

[87] Monster Energy Sign-In Page, http://www.monsterenergy.com/signin.php (last visited Aug. 12, 2009).

[88] Liquid Lightning Energy Drink Home Page, http://www.llenergy.com/ (last visited Aug. 12, 2009).

[89] Amp Energy Home Page, http://www.ampenergy.com/ (last visited Aug. 12, 2009).

B. Problems with Caffeine

In the nineteenth century, in an attempt to appeal to the weary American public, Coca-Cola promoted the beverage by promising a refreshing drink that would "help the tired brain and relieve exhaustion."[90] Despite the risks associated with caffeine, it remains the most commonly used (and abused) drug in the nation.[91] Although studies warning of the potentially adverse health effects of this psychoactive[92] drug began surfacing as early as the 1960s,[93] caffeine has remained legal and mostly unregulated. While many consumers may be aware of the fact that too much caffeine can aggravate existing conditions, such as hypertension or heart disease, most do not know how much is "too much." Consumers are often unaware of the "hidden" caffeine content in the foods they eat.[94] For example, most people are unaware that a small serving of Häagen-Dazs' coffee ice cream actually has more caffeine than a Coke.[95] Furthermore, as caffeine content in products continues to increase, public awareness about it seems to be disturbingly low. As a result, the public remains largely unaware that overconsumption of these products can cause substantial harm.

1. The Potential for Caffeine Toxicity

One of the attractions to caffeine is based on its short-term effects, often called a caffeine "lift."[96] As a powerful stimulant, the effects of caffeine can be felt within fifteen minutes and typically last for about five hours after ingestion.[97] However, because caffeine can linger in the body for up to

---

[90] BIGELOW & EDGAR, *supra* note 60, at 139.

[91] WEINBERG & BEALER, *supra* note 1, at 198-200.

[92] Kenneth S. Kendler & Carol A. Prescott, *Caffeine Intake, Tolerance, and Withdrawal in Women: A Population-Based Twin Study*, 156 AM. J. PSYCHIATRY 223 (1999) ("Caffeine is by far the most commonly consumed psychoactive substance.").

[93] BIGELOW & EDGAR, *supra* note 60, at 141.

[94] *See* Interview by Daryn Kagan with Sanjay Gupta, CNN Medical Correspondent, *Caffeine Hidden in Many Foods*, CNN (June 27, 2003), partial transcript *available at* http://edition.cnn.com/2003/health/diet.fitness/o6/27/otsc.gupta/index.html (last visited Sept. 25, 2009).

[95] *Id.*

[96] Larry J. Birnbaum & Jacob D. Herbst, *Physiologic Effects of Caffeine on Cross-Country Runners*, 18 J. STRENGTH AND CONDITIONING RES. 463, 463 (2004).

[97] BIGELOW & EDGAR, *supra* note 60, at 142-43.

twelve hours,[98] toxicity (overdose) is a serious concern, especially in light of the high caffeine content of some of the latest products on the market. Caffeine intoxication is a recognized clinical syndrome included in the American Psychiatric Association's, *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV-TR)[99] and the World Health Organization's International Classification of Mental and Behavioral Disorders (ICD-10).[100] Common features of caffeine intoxication include insomnia, diuresis, muscle twitching, tachycardia, arrhythmia, and gastrointestinal disturbance.[101]

The toxicity concern may not cross the mind of the "cup a day" coffee drinker, since toxic effects usually do not become evident until a drinker has consumed approximately 520mg of caffeine in a day. However, in light of the excessively high caffeine content found in some brands of coffee and energy drinks,[102] this threshold may be very easily reached and exceeded.

This increased likelihood of toxicity from energy drink consumption may be attributed primarily to three reasons. First, energy drinks lack adequate labeling of caffeine content.[103] As a result, consumers are simply unable to keep track of the amount of caffeine they are ingesting over the course of the day. Second, many of the leading energy drinks are marketed with claims of performance enhancing effects,[104] which may lead to overuse. For example, Red Bull promises its consumers a range of benefits including "increase[d] performance," "concentration and reaction speed," and

---

[98] WEINBERG & BEALER, *supra* note 1, at 221 ("[M]ore than 90 percent has been removed from the body in about twelve hours."). Also note than an individual's metabolism of caffeine may be influenced by several factors including the presence of alcohol in the body, race, gender, age, presence of oral contraceptives in the body, liver damage, or pregnancy. *Id.* at 220.

[99] AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS: DSM-IV 232 (4th ed. 2000) [hereinafter DSM-IV].

[100] WORLD HEALTH ORG., THE ICD-10 CLASSIFICATION OF MENTAL AND BEHAVIORAL DISORDERS: CLINIC DESCRIPTIONS AND DIAGNOSTIC GUIDELINES (2007), *available at* http://apps.who.int/classifications/apps/icd/icd10online/ [hereinafter WHO ICD-10 CLASSIFICATION].

[101] AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS: DSM-IV 232 (4th ed. 2000).

[102] *See* CSPI Caffeine Contents, *supra* note 43; Energy Fiend, *supra* note 33; *see also* 21 C.F.R. § 182.1180 (2007).

[103] *See* Prothro, *supra* note 13, at 83-84.

[104] *See, e.g.*, Monster Energy, *supra* note 87; Liquid Lighting, *supra* note 88; Amp Energy, *supra* note 89.

"stimulate[d] metabolism."[105] Based on these descriptions, consumers may reasonably believe that "more is better," and drink more than one serving at a time. The third reason involves consumer demographics. "Since there are no restrictions on the sale of energy drinks, adolescents and children (who may be inexperienced and less tolerant to the effects of caffeine) may be at an increased risk for caffeine intoxication."[106] This last reason also applies to caffeine pills, which are sold without any age restrictions. Even if spaced out by a few hours, a combination of caffeine pills and other caffeinated drinks, especially coffee or an energy drink, can easily result in toxicity.

While the possibility of caffeine overdose may appear remote to most consumers, the statistics reveal that caffeine overdose is very common, especially among young people. According to a study by Northwestern University, one U.S. poison control center received over 250 calls pertaining to caffeine overdose in a three-year period.[107] This averages out to about one or two calls a week. More alarming is that the average age of the callers was twenty-one.[108] These findings are not unique. Of the fifty-one percent of college students who reported consuming energy drinks,[109] twenty-nine percent reported "weekly jolt and crash episodes,"[110] twenty-two percent reported headaches, and nineteen percent reported heart palpitations.[111] Further, several studies have revealed numerous cases in which the consumption of energy drinks has been linked to seizures,[112] acute mania,[113] stroke,[114] and sudden death due to heart failure.[115]

---

[105] Red Bull Energy Drink Benefits, http://www.redbull.com/cs/Satellite /en_INT//Products/011242745950125#/product-Benefits (last visited Sept. 27, 2009).

[106] Reissig et al., *supra* note 11, at 5.

[107] Danielle M. McCarthy et al., *Hospitalization for Caffeine Abuse is Associated with Abuse of Other Pharmaceutical Products*, 26 AM. J. EMERGENCY MED. 799, 800 (2008).

[108] *Id.* at 799.

[109] *See* Malinauskas et al., *supra* note 50, at 3.

[110] *Id.*

[111] *Id.*

[112] Reissig et al., *supra* note 11, at 5.

[113] *Id.*

[114] *Id.*

[115] *Id.*

Vulnerability to caffeine intoxication is significantly affected by one's level of tolerance.[116] According to numerous studies, daily consumption of 750mg or more can produce a variable level of tolerance to caffeine's "subjective, pressor, and neuroendocrine effects."[117] For this reason, children and adolescents who may not use caffeine on a daily basis are much more likely to overdose from energy drink consumption.[118]

Sensitivity to caffeine may also depend on factors over which an individual has relatively little control, such as body mass and stress level.[119] Those with lower body masses are likely to feel the effects of caffeine sooner than those with higher masses.[120] All forms of stress, including psychological and heart stress, can also increase one's sensitivity to caffeine.[121]

Several studies have presented compelling evidence that regular caffeine consumption may also result in substance dependency.[122] These studies, which involved both adults[123] and adolescents,[124] have demonstrated an inability to quit, despite experiences of physical harm and withdrawal symptoms.

Although caffeine is not regulated as a dangerously addictive substance, the set of symptoms commonly associated with caffeine withdrawal is well documented in medical literature.[125] Caffeine withdrawal is listed as an official

---

[116] *Id.* at 6 ("Tolerance refers to a decrease in responsiveness to a drug as a result of drug exposure.").

[117] Reissig et al., *supra* note 11, at 6. A "pressor" is a substance capable of raising one's blood pressure. *Id.* "Neuroendocrine" refers to interactions between the nervous system and the endocrine system. *Id.*

[118] *Id.*

[119] Louisiana State University Agricultural Center, *Do We Need to Re-Think Our Drinks* (2008), http://www.lsuagcenter.com/en/food_health/nutrition/Do+we+need+to+rethink+our+drinks.htm [hereinafter LSU].

[120] PreventDisease.com, *Should You Decaffeinate Your Diet?* July 17, 2006, http://preventdisease.com/home/weeklywellness282.shtml (last visited Oct. 14, 2009).

[121] LSU, *supra* note 119.

[122] *See generally* R.R. Griffiths et al., *Low-Dose Caffeine Discrimination in Humans*, 252 J. PHARMACOL. EXP. THER. 970, 971 (1990); Oberstar, *supra* note 84, at 130-32 (discussing empirical results of a caffeine dependence and withdrawal study); K. Silverman et al., *Low-Dose Caffeine Discrimination and Self-Reported Mood Effects in Normal Volunteers*, 57 EXP. ANAL. BEHAV. 91, 93 (1992).

[123] *See generally* Griffiths et al., *supra* note 122, at 971; Silverman et al., *supra* note 122, at 92.

[124] *See generally* Oberstar, *supra* note 84, at 132-33.

[125] *See, e.g.*, Juliano & Griffiths, *supra* note 28. ("Although reports of caffeine withdrawal in the medical literature date back more than 170 years, the most rigorous experimental investigations of the phenomenon have been conducted only recently.").

diagnosis in *ICD-10*,[126] and a research diagnosis in *DSM-IV*.[127] These symptoms, which occur when a person who regularly consumes as little as 100mg stops her consumption, can include irritability, muscle aches, extreme fatigue, and impaired concentration.[128] Perhaps the most widely experienced withdrawal symptom is headache,[129] which can range from moderate to severe[130] or occasionally develop into migraines. Other symptoms of caffeine withdrawal include fatigue, blurred vision, decreased desire to socialize, flu-like symptoms, irritability, confusion, nausea, and muscle pain.[131] As high as thirteen percent of coffee addicts experienced "clinically significant distress" when their daily caffeine source was removed.[132]

2. Dangerous Combinations with Alcohol

Dangerous combinations of caffeine and alcohol such as a cocktail combining Red Bull and vodka have gained popularity recently, especially among young people.[133] According to a survey of college students who had recently consumed as little as one energy drink, twenty-seven percent reported mixing it with alcohol.[134] Of those that did so, almost half used more than three energy drinks on one single occasion.[135] Moreover, beer companies are attempting to respond to this trend of "mixing" by offering pre-mixed concoctions of alcohol and caffeine.[136]

---

[126] *See* WHO ICD-10 CLASSIFICATION, *supra* note 100, F.15.3 ("Mental and behavioural disorders due to use of other stimulants, including caffeine").

[127] *See* DSM-IV, *supra* note 99, at 234.

[128] Peters, *supra* note 36.

[129] M. J. Shirlow & C.D. Mathers, *A Study of Caffeine Consumption and Symptoms: Indigestion, Palpitations, Tremor, Headache and Insomnia*, 14 INT. J. OF EPIDEMIOLOGY 239, 240-41 (1985).

[130] *Id.* at 246.

[131] Juliano & Griffiths, *supra* note 28, at 12-17.

[132] *Id.* at 25.

[133] LSU, *supra* note 119.

[134] *See* Malinauskas et al., *supra* note 50, at 4.

[135] *Id.*

[136] Antonio Velarde, *Man Wants to Take Fizz Out of Caffeinated Alcoholic Drink: Spring Plans to Sue After Daughter Suffers an Allergic Reaction After Drinking a MillerCoors Energy Beer*, WILSON TIMES (Wilson, North Carolina), Dec. 1, 2008, *available at* http://wilsondaily.com/News/Local/Story/Man-wants-to-take-fizz-out-of-caffeinated-alcoholic-drink--; *see also* Peter Carlson, *Bartender, Pour Me Another Cup*, WASH. POST, Jan. 30, 2005, at C1.

Mixing alcohol and caffeine can be dangerous because energy drinks are stimulants and alcohol is a depressant. As such, this combination can mask the intoxicating effects of alcohol. Research shows that ingestion of Red Bull with vodka reduced the consumers' perception of impairment of motor coordination more so than the vodka alone.[137] Thus, according to research, when mixing energy drinks and alcohol, users may not be able to accurately gauge their own level of intoxication, increasing the likelihood of an alcohol-related injury[138] or a DUI.[139] In a 2006 survey, college students who had consumed "combinations" of energy drinks and alcohol had a "significantly higher prevalence of alcohol related consequences" than those who had consumed just alcohol.[140]

The dehydrating effect of such mixers is also troubling. Since caffeine, like alcohol, is a diuretic, the combination of the two leads to increased loss of fluid.[141] This dehydration can then hinder the body's ability to metabolize alcohol, thus increasing its toxicity.[142] Such cases, although rare, are not unheard of. For example, in 2006, a young Swedish woman died after consuming a mixed drink containing Red Bull, apparently of dehydration.[143]

Moreover, contrary to myth, caffeine cannot help a drunken person quickly become sober.[144] Nor can caffeine help neutralize the effect of an overdose of a sedative.[145] In fact, it can actually have a contrary effect, by altering the rate of absorption in the digestive system. Furthermore, "consuming caffeine in combination with . . . alcohol can delay the body's ability to rid itself of the caffeine."[146]

---

[137] Sionaldo Eduardo Ferreira et al., *Effects of Energy Drink Ingestion on Alcohol Intoxication*, 30 ALCOHOLISM: CLINICAL & EXPERIMENTAL RES. 598, 598 (2006).

[138] *See generally* Cocktails, *supra* note 9.

[139] *Caffeinated Alcohol Drinks May Lead to DUI*, http://www.dui.com/dui-library/related/caffeine-alcohol-masks-dui (last visited Jan. 17, 2009).

[140] *See* Cocktails, *supra* note 9, at 455-59.

[141] *'Energy Drinks' Stir Health Debate*, ASSOCIATED PRESS, Dec. 20, 2007, *available at* http://www.intelihealth.com/IH/ihtIH/WSIHW000/333/8015/344084.html (last visited Oct. 15, 2009).

[142] LSU, *supra* note 119.

[143] *'Energy Drinks' Stir Health Debate*, *supra* note 141.

[144] BIGELOW & EDGAR, *supra* note 60, at 146.

[145] *Id.*

[146] *Id.*; *see also* WEINBERG & BEALER, *supra* note 1, at 219-20 (discussing the effects of several variables on the rate of caffeine metabolism in humans).

3. Other Adverse Effects

Finally, caffeine has been noted to have additional adverse effects and consequences. Caffeine has also been shown to react negatively with certain medications, including acne medications, which are commonly used by young people.[147] As a general practice, most physicians now advise pregnant women to eliminate all caffeine from their diets during pregnancy.[148] This is especially true for women who have miscarried in the past.[149] Studies show that babies born to women who consume excessive amounts of caffeine during pregnancy have delayed growth, as well as problems with mental and physical development.[150]

Some researchers have voiced growing concern over whether caffeine serves as a gateway to other forms of drug use.[151] One study found that college students who regularly consumed energy drinks were much more likely to use nonmedical prescription stimulants in the future.[152]

Moreover, energy drinks cause concerns for athletes. While these drinks generally provide some athletic benefits such as increased endurance, consumption of caffeine may be exceptionally dangerous while exercising. This is because caffeine can cause dehydration,[153] as well as an increase in blood pressure and heart rate.[154] Combined with the exertion of

---

[147] *The Dangers of Energy Drinks and How They Might Affect You*, www.healthmad.com/nutrition/the-dangers-of-energy-drinks-and-how-they-might-affect-you.54959 (last visited January 18, 2009).

[148] BIGELOW & EDGAR, *supra* note 60, at 145-46.

[149] *Id.*

[150] *See generally* CARE Study Group, *Maternal Caffeine Intake During Pregnancy and Risk of Fetal Growth Restriction: A Large Prospective Observational Study*, 337 BRITISH MED. J. 1334 (2008); Nobuo Momoi et al., *Modest Maternal Caffeine Exposure Affects Developing Embryonic Cardiovascular Function and Growth*, 294 AM. J. PHYSIOLOGY: HEART AND CIRCULATORY PHYSIOLOGY H2248 (2008); Jorn Olsen & Bodil Hammer Bech, *Caffeine Intake During Pregnancy*, 337 BRITISH MED. J. 1305 (2008); Isabel Fortier, et al., *Relation of Caffeine Intake During Pregnancy to Intrauterine Growth Retardation and Preterm Birth*, 137 AM. J. EPIDEMIOLOGY 931 (1993).

[151] Jill U. Adams, *Energy Drinks: A Dangerous, Edgy Buzz?*, L.A. TIMES, Oct. 13, 2008, at F3.

[152] Arria et al., *Energy Drink Use is Associated With Subsequent Non-Medical Prescription Stimulant Use Among College Students*, PROC. OF THE AM. PUBLIC HEALTH ASS'N ANN. MEETING (2008).

[153] FDA AND YOU, *supra* note 11.

[154] *Id.*

prolonged rigorous activity, caffeine consumption can pose serious threats to athletes.[155]

II. CAFFEINE REGULATION

Since the introduction of Coca-Cola in 1886,[156] many soft drink manufacturers have used kola nuts, a source of caffeine, to flavor their products. As Coca-Cola gained popularity, the FDA became concerned about food adulteration and the health of the nation's children.[157] The conflict between caffeine's purveyors and detractors came to a head in the early 1900s, when the government initiated a federal lawsuit against Coca-Cola, seeking to remove caffeine from its formula.[158] The district court judge directed a jury verdict for Coca-Cola, ruling that "because caffeine had been part of the original formula or recipe for the beverage, it could not be legally regarded as an additive."[159] After the lower courts held for Coca-Cola, two bills were introduced to amend the Pure Food and Drugs Act by adding caffeine to the list of 'habit-forming' and 'deleterious' substances that must be listed on the label.[160] According to one author, "Coca-Cola successfully fought to kill the bills, the first of many such efforts to keep its caffeine content out of the public eye."[161] Meanwhile, the government appealed the District Court's ruling to the Supreme Court,[162] where the Court held that caffeine was in fact an additive. However, this was just the beginning of the caffeine controversy, and for the remainder of the century, Congress and the FDA struggled to determine the safety of caffeine and define its place in our society.

---

[155] Peters, *supra* note 36.

[156] Coca-Cola Website, http://www.thecoca-colacompany.com/heritage/chronicle_birth_refreshing_idea.html (last visited August 12, 2009).

[157] WEINBERG & BEALER, *supra* note 1, at 187.

[158] United States v. Forty Barrels & Twenty Kegs of Coca-Cola, 191 F. 431 (E.D. Tenn. 1911), *aff'd*, 215 F. 535 (6th Cir. 1914), *rev'd*, 241 U.S. 265.

[159] WEINBERG & BEALER, *supra* note 1, at 189.

[160] MARK PENDERGRAST, FOR GOD, COUNTRY AND COCA-COLA 119 (Basic Books 2000) (1993).

[161] *Id.*

[162] United States v. Forty Barrels & Twenty Kegs of Coca-Cola, 241 U.S. 265 (1916).

A. Early FDA Regulation of Caffeine as a "Food Additive"

The Food, Drug, and Cosmetic Act of 1938[163] (FDCA) granted the FDA broad authority to oversee the safety of foods, drugs, and other products such as cosmetics, in order to protect the public health.[164] Under the FDCA, a "food" is defined as any article "used for food or drink . . . and articles used for components of any such article."[165] A "drug" is defined as any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease."[166] In classifying a substance as a food or drug, the FDA and courts have traditionally looked to several factors. These include (1) whether the substance is intended to affect the body's structure or its function; and (2) the specific intent of the vendor, which may be inferred from the product's labeling and advertising material.[167] This distinction has traditionally been critical, since foods are subject to lesser scrutiny by the FDA than drugs.[168] Depending on the form it takes, caffeine has been regulated under both definitions.

In 1958, Congress passed the Food Additive Amendments to the FDCA,[169] which required the FDA to evaluate the safety of all food additives. Pursuant to these amendments, the FDA required manufacturers that added caffeine to their foods and beverages to include "caffeine" in the list of ingredients on the product's label.[170] The FDA did not, however, require these manufacturers to disclose the precise quantity of caffeine contained in these products.

---

[163] 21 U.S.C. §§ 301-399a (2006).

[164] *See generally id.* § 346.

[165] *Id.* § 321(f).

[166] *Id.* § 321(g)(1).

[167] *See* Nat'l Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 333-34 (2d Cir. 1977) ("The vendor's intent in selling the product to the public is the key element in this statutory definition."). In determining vendor intent, the FDA considers "labeling, promotional material, advertising, and 'any other relevant source.'" *Id.* (internal quotation marks omitted); *see also* Rutherford v. United States, 542 F.2d 1137, 1140 (10th Cir. 1976); Nat'l Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 789 (2d Cir. 1974); United States v. An Article . . . Consisting of 216 Cartoned Bottles . . . More or Less, of an Article Labeled in part: "Sudden Change," 409 F.2d 734, 739 (2d Cir. 1969); United States v. Hohensee, 243 F.2d 367, 370 (3rd Cir. 1956); Hanson v. United States, 417 F. Supp. 30, 34 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976); United States v. 2 Cartons, More or Less, No. 26 Formula GM, 132 F. Supp. 569, 573 (S.D.Cal.1952).

[168] *Id.*

[169] 21 U.S.C. § 348.

[170] *Id.*

The requirement of listing caffeine on the ingredients list was lifted in 1961 when the FDA classified caffeine as "Generally Recognized As Safe" ("GRAS").[171] This designation generally means that an additive substance is considered safe by experts, and is therefore exempt from the usual FDCA food additive requirements.[172] As a result, the FDA did not have to evaluate caffeine as added to foods.[173]

However, under this amendment, a substance can only hold GRAS status so long as it has a "long, safe history of common use in foods, or . . . is determined to be safe based on proven science."[174] If new evidence surfaces to suggest that such a substance may no longer be safe, the FDA has the authority to "prohibit its use or require further studies to determine its safety."[175]

Furthermore, the FDA still required that manufacturers that added caffeine to sodas did so "in accordance with good manufacturing practice."[176] According to statutory standards, this means that "[t]he quantity of a substance added to food [may] not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food."[177] Interestingly, the health-prioritizing idea behind this standard has not been extended to apply to dietary supplements.[178]

Notably, caffeine that is naturally present in ingredients used in the production process, such as coffee beans used to make coffee, is not considered to be a food additive and thus has never needed to appear on a product label. As a team of researchers at Johns Hopkins University noted, "[t]he regulation of beverages to which caffeine is added has been

---

[171] 26 Fed. Reg. 938, 940 (Jan. 31, 1961) (codified at 21 C.F.R. pt. 121).

[172] 21 U.S.C. § 321(s).

[173] Carol Rados, *GRAS: Time-Tested, and Trusted, Food Ingredients*, FDA CONSUMER MAG., March-April 2004, *available at* http://www.mass.gov/Eeohhs2/docs/dph/environmental/foodsafety/reporters05.pdf (last visited Oct. 15, 2009). "At the time, knowledge about food science and the potential long-term harmful effects of food chemicals on health were beginning to surface. Congress decided it was not necessary for the food industry to prove the safety of substances such as salt, sugar, and spices intentionally added to foods if they were already generally regarded as safe by qualified scientists." *Id.*

[174] *Id.*

[175] *Id.*

[176] 21 C.F.R. § 182.1180(c) (2009).

[177] *Id.* § 182.1(b)(1) (2009).

[178] *See generally infra* notes 188-198 and accompanying text (discussing the immediate implication of the passage of the Dietary Supplement Health and Education Act of 1994).

challenging, partly because of the widespread and long-term use of beverages such as coffee and tea in which caffeine is a natural constituent."[179]

B. Recent Regulation: Caffeine as a Dietary Supplement

In 1980, concerns over the safety of using caffeine as an additive started to re-surface.[180] Citing these health concerns, the FDA considered deleting caffeine from the GRAS list, and proposed a requirement that manufacturers of soft drinks refrain from adding caffeine.[181] Again, manufacturers responded that they were adding caffeine to soft drinks solely on the basis of its supposed flavor-enhancing qualities.[182] Since scientific research on the effects of caffeine was not conclusive, the FDA succumbed to this argument. Interestingly, researchers contend that "[i]f caffeine had not been accepted as a flavor enhancer, but had been regarded as a psychoactive ingredient, soft drinks might have been regulated by the FDA as drugs."[183] Instead, the FDA limited the amount of caffeine that a manufacturer of cola-type drinks could add to its products. Currently, these manufacturers are limited to producing beverages with no more than approximately 70 mg per 12 fluid ounces.[184]

While this limitation might reasonably have been expected to keep excessively caffeinated and potentially harmful beverages off the shelves, new legislation brought substantial change. In 1994, as a result of intense lobbying by various industries,[185] Congress passed the Dietary Supplement

---

[179] Reissig et al., *supra* note 11, at 2.

[180] Caffeine; Deletion of GRAS Status, Proposed Declaration That No Prior Sanction Exists, and Use on an Interim Basis Pending Additional Study. 45 Fed. Reg. 69,817, 69,821 (Oct. 21, 1980) (to be codified at 21 C.F.R. pts. 180, 182).

[181] *Id.*

[182] Roland R. Griffiths & Ellen M. Vernotica, *Is Caffeine a Flavoring Agent in Cola Soft Drinks?* 9 ARCH. FAM. MED. 727, 728 (2000) (citing PepsiCo Inc., *The physical or technical effect of caffeine in cola beverages*, July 20, 1981, Vol. III, Appendix XII of Comments of the National Soft Drink Association submitted to the Department of Health and Human Services, Food and Drug Administration in response to the proposal to delete caffeine in cola-type beverages from the list of substances generally recognized as safe and to issue an interim food additive regulation governing its future use, Jul. 29 1981 (FDA Docket No. 80N-0418)).

[183] Reissig et al., *supra* note 11, at 2.

[184] 21 C.F.R. § 182.110(b) (2009) (containing a .02% limit, which amounts to approximately 70mg of caffeine per 12 ounces of fluid).

[185] *See generally* Lauren J. Sloane, *Herbal Garden of Good and Evil: The Ongoing Struggles of Dietary Supplement Regulation*, 51 ADMIN L. REV. 323 (1999).

Health and Education Act (DSHEA).[186] The purpose of this act was:

> [To create a] unique regulatory framework in an attempt to strike the right balance between providing consumers access to dietary supplements that they may choose to use to help maintain and improve their health, and giving FDA the necessary regulatory authority to take action against supplements . . . that present safety problems, have false or misleading claims, or are otherwise . . . misbranded.[187]

Congress defined a "dietary supplement" as a product taken by mouth that contains "dietary ingredients"[188] intended to supplement the diet.[189] While the FDA had initially included in this category only essential nutrients—i.e., vitamins, minerals and proteins—DSHEA expanded the term to encompass all kinds of substances, including ingredients that would otherwise qualify as drugs.[190] Thus, as long as a product, like caffeine, was marketed as a "dietary supplement," it would be considered as such by the FDA.[191]

This self-declared designation is important because substances classified as dietary supplements are not subject to the same type of scrutiny with respect to labeling as drugs.[192] For dietary supplements, manufacturers only have to ensure that product label information is "not false or misleading."[193] The only specific labeling requirement arises when the product label includes a claim that it affects the body's function.[194] In that event, the label must also disclaim "that the product is not intended to diagnose, treat, cure, mitigate, or prevent any

---

[186] 21 U.S.C. § 301 (2006).

[187] *Regulation of Dietary Supplements Particular Those Containing: Ephedra or Ephedrine Alkaloids: Hearing Before the Subcomm. on Commerce, Trade and Consumer Protection and the Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce*, 108th Cong. 1 (2003) [hereinafter McClellan Statement], (statement of Mark B. McClellan, M.D., Ph.D., Comm'r of the Food and Drug Administration).

[188] 21 U.S.C. § 321(ff) (2006). This may include vitamins, minerals, herbs or other botanicals, amino acids, and dietary substances such as enzymes. *Id.*

[189] *Id.*

[190] *Id.*

[191] *Id.*

[192] *Id.* (stating that dietary supplements are deemed foods instead of drugs for the purposes of regulation).

[193] FDA, OVERVIEW OF DIETARY SUPPLEMENTS, http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm, (last visited Sept. 30, 2009) [hereinafter Overview].

[194] *Id.*

disease."[195] The purpose of this disclaimer is to inform the consumer that the product is not considered by the FDA to be a drug, as one might otherwise expect.[196]

Under DSHEA, the FDA bears the responsibility for taking action against any supplements deemed unsafe after being marketed.[197] However, manufacturers do not need to register their products with the FDA, or receive any sort of approval prior to production or marketing.[198]

C. Problems with the Dietary Supplement Health and Education Act

With the categorical separation of dietary supplements from other foods, these supplements lost almost all of the safeguards that had traditionally applied to food and drug products. Subsequently, Congress did not equip the FDA with adequate tools to execute its stated objective of keeping consumers healthy. These shortcomings are threefold, and particularly exacerbate the health concerns surrounding caffeine overuse.

First, DSHEA does not actually give the FDA any way to assess the safety of these products before they hit the shelves, since the FDA has no authority to approve these supplements before they are marketed.[199] Thus, under the Act, the manufacturing companies have the sole responsibility for determining that their supplements are safe. Since it was passed in 1994, this imbalanced allocation of responsibility has been severely criticized.[200] In 2007, the FDA announced a "final rule" that "establish[ed] regulations . . . requir[ing] current good manufacturing practices (cGMP) for dietary

---

[195] McClellan Statement, *supra* note 187.

[196] *See* Overview, *supra* note 193.

[197] *Id.*

[198] *Id.*

[199] *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.); *see also Hearing on Dietary Supplements: Hearing Before the Subcomm. on Commerce, Trade and Consumer Protection and the Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce*, 106th Cong. 1-3 (1999) (statement of Rep. Henry A. Waxman, Ranking Member, *available at* http://oversight.house.gov/documents/20050124104631-14776.pdf) [hereinafter Waxman].

[200] *See generally* Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663 (1997); Jennifer Akre Hill, *Creating Balance: Problems Within DSHEA and Suggestions for Reform*, 2 J. FOOD L. & POL'Y 361 (2006); Iona N. Kaiser, *Dietary Supplements: Can the Law Control the Hype*, 37 HOUS. L. REV. 1249 (2000).

supplements."[201] However, the obligations of supplement manufacturers are limited to testing the purity of their products and verifying that the product actually contains what its label says it does.[202] While this may be a step in the right direction, there is still little assurance that dietary supplements do what they claim to, or that they are safe.[203] Further, the testing is left largely to the discretion of manufacturing companies, and the FDA has stated that it will not inspect all plants to monitor compliance.[204]

Second, even if a safety issue is discovered, the FDA is held to the very high threshold of demonstrating a "significant or unreasonable risk of illness or injury" before it can remove an unsafe supplement from the market.[205] The Act does not contain any guidelines as to what may constitute "a significant and unreasonable risk of illness or injury." Nonetheless, this seems like "a higher threshold [for removing a product from the market] than for foods, drugs, or medical devices."[206] Recent experiences indicate that this may be too high of a burden to place on the FDA before it can act. In 2004, because of the FDA's lack of authority to require pre-market safety testing or intervene at a lower threshold of reported adverse effects, Ephedra caused dozens of deaths before it was pulled off the market.[207] After reviewing the scientific evidence, the FDA ultimately found that Ephedra-containing supplements present an unreasonable risk of illness.[208]

---

[201] Press Release, FDA, FDA Issues Dietary Supplements Final Rule (June 22, 2007), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108938.htm.

[202] *See id.*

[203] Todd Zwillich, *FDA OKs Dietary Supplement Regulations Companies Left to Set Their Own Testing Standards*, WEBMD HEALTH NEWS, June 22, 2007, http://www.webmd.com/news/20070622/fda-oks-dietary-supplement-regulations (last visited Jan. 28, 2009) (quoting Sidney Wolfe, MD, Health Director, Public Citizen, FDA watchdog group).

[204] *See id.* (statement from Vasilios Frankos, Ph.D., director of FDA's office of dietary supplements) ("We leave it to the firm to have a scientifically valid testing program").

[205] *Hearing on Ephedra and FDA's Dietary Supplement Adverse Event Reporting System: Hearing Before the Subcomm. on Commerce, Trade and Consumer Protection and the Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce*, 106th Cong. 1 (1999) (statement of Rep. Henry A. Waxman, Ranking Member), *available at* http://oversight.house.gov/documents/20050124104606-35057.pdf.

[206] *Id.*

[207] Mark Moran, *Did Delay of Ephedra Ban Cause Unnecessary Deaths?* 39:3 PSYCHIATRIC NEWS 34 (Feb. 6, 2004), *available at* http://pn.psychiatryonline.org/cgi/content/full/39/3/24.

[208] FDA Import Alert #54-13, Detention Without Physical Examination of Dietary Supplements and Bulk Dietary Ingredients Containing Ephedrine Alkaloids

Third, while all drug and medical companies are required to report any adverse events relating to their products, the "regulation" of dietary supplements merely involves a "voluntary" adverse event reporting system. This results in the very dangerous possibility of manufacturers becoming aware of safety problems with their products, yet failing to volunteer this information to the FDA. In 2002, the Department of Justice initiated a criminal investigation into the failure of Metabolife International, a manufacturer of dietary supplements containing hazardous forms of Ephedra, to report adverse reactions to the FDA.[209] Moreover, even if this system is respected, the manufacturers could still delay the process of removing the product from the market by dragging their feet in self-reporting safety problems. For example, in 2002, when Metabolife finally acquiesced to the FDA's requests for information, it turned over more than 14,700 health complaints.[210]

These deficiencies with the FDA's current regulatory scheme raise serious concerns about its ability to address the safety problems surrounding caffeine consumption. DSHEA gives manufacturers of caffeine-containing products excessive leeway over their own fates. For example, if one manufacturer "markets a caffeinated soft drink as just a soft drink, it will likely be regulated as a food."[211] But if one markets this same soft drink as a functional product, it will be classified as a dietary supplement and escape the pre-market approval process required of drugs.[212]

Furthermore, because of the nature of caffeine as a natural stimulant, virtually any food or beverage that adds caffeine can make some sort of "functional" claim and market its product as a dietary supplement. Because the "lift" function

---

from All Countries (Jul. 13, 2004), *available at* http://www.accessdata.fda.gov/ImportAlerts/ora_import_ia5413.html.

[209] Ellen Coleman, *Ephedrine-Containing Supplements*, GSSI SPORTS SCIENCE NEWS, *available at* http://www.miaa.net/student-services/ephedrine_email.pdf. (last visited Oct. 16, 2009).

[210] Penni Crabtree, Court Orders Keep Hidden Complaints against San Diego-Based Metabolife, THE SAN DIEGO UNION-TRIBUNE KNIGHT RIDDER/TRIBUNE BUSINESS NEWS, Sept. 8, 2002, *available at* http://findarticles.com/p/articles/mi_hb5553/is_200209/ai_n21669258/ (last visited Oct. 16, 2009).

[211] Prothro, *supra* note 13, at 76 (internal quotation marks omitted).

[212] Joan Long, *How Sweet It Is: Energy Drinks or Liquid Candy?*, HEALTHCARE LEDGER 14, Nov. 2008, *available at* http://www.healthcareledger.com/november2008/How%20Sweet%20It%20Is%20Energy%20Drinks%20or%20Liquid%20Candy%20Nov%202008.pdf (stating that "[s]ome drinks are classified as a dietary supplement in order to contain high levels of caffeine").

is in such high demand and brands compete on the basis of caffeine content,[213] manufacturers can escape regulation and increase sales at the same time by marketing their products in this way.

While manufacturers of soda-type beverages initially complied with the limits placed on their products under the Food Additives Amendments,[214] the effectiveness of compliance has dramatically changed with the advent of the "energy drink." Red Bull, introduced in the United States in 1997,[215] contains 80mg of caffeine in an 8.46-ounce can.[216] As the first contemporary energy drink, Red Bull exceeded the FDA's caffeine limits for cola beverages, and was able to do so by claiming to fall under the umbrella of dietary supplements. Given the success of Red Bull, more and more companies sought to "develop and position . . . product[s] in th[is] categor[y] so they [were] not considered drugs or medical foods."[217] As a result, today, "[a]t least 130 energy drinks now exceed 0.02 [percent] caffeine" content.[218]

Because these energy drinks constitute dietary supplements, a manufacturer need only establish that its products do in fact contain relatively high levels of uncontaminated caffeine in order to stay consistent with a label promising a serious "boost." The toxicity issue never comes before the FDA. If it does, it will only be because someone has been seriously hurt. Yet, even if individuals become seriously hurt, it does not necessarily mean FDA regulation will result, as it cannot compel admissions of adverse reactions from supplement manufacturers.

D. Regulation of Caffeine as a Drug

The FDA also regulates caffeine as a stimulant in some over-the-counter drug products.[219] These products fall within

---

[213] *See* discussion on competition based on high caffeine content, *supra* notes 37-38 and accompanying text.

[214] See discussion of Food Additives Amendment, *supra* notes 169-170 and accompanying text.

[215] *See* Red Bull Website, *supra* note 4.

[216] *See* Energy Fiend, *supra* note 33.

[217] Morgan, Lewis & Bockius, LLP, Dietary Supplements and Functional Foods, http://www.morganlewis.com/index.cfm/fuseaction/practiceArea.detail/nodeID/38e7263b-6865-4319-bd79-0d86dfd42550/practiceAreaID/1C2A3B06-4482-4457-BDE2-D0AF22DC7D50/ (last visited Oct. 1, 2009) [hereinafter Morgan Lewis].

[218] Reissig, *supra* note 11, at 2 (citing Energy Fiend, *supra* note 33).

[219] *See* 21 C.F.R. § 310.545 (a) (20) (2007).

the "drug" category, and are generally subject to much greater regulation.[220] The FDA requires "extensive showings of safety and effectiveness before it will allow" these products to be marketed.[221] The moderate use of caffeine as a stimulant drug has been found safe and effective for most people.[222] Thus, products such as No Doz or Vivarin disclose quantities on their labels.[223] However, despite enhanced regulation and labeling requirements in this area, labels are often ignored by the public and the pills are overused.

Abuse of over-the-counter pills has only increased with the rise in popularity of energy drinks. Given the inconsistent labeling requirements of over-the-counter pills and energy drinks, many young people may equate the two as simply different forms of caffeine. This concern might be exacerbated by the aggressive marketing of unlabeled energy drinks to youth, thus creating a pre-addicted market for caffeine pills. Logically, there is little reason for the public to believe that a caffeine pill containing 200mg of caffeine, sold in a "labeled" box, could cause any more harm than the "unlabeled" energy drink that contains 500mg of the same exact substance. It should be no surprise that a consumer may ignore the label and take two or more pills because he thinks it's still "better" than a can of BooKoo, which contains more caffeine and doesn't even have a warning label. Thus, although the FDA does regulate one aspect of the caffeine industry with greater scrutiny, the very inconsistency of its approach to caffeine in general renders this relatively higher regulation largely ineffective.

In sum, the government's regulatory shift in enacting DSHEA does not reflect growing concern over caffeine consumption. According to one report, "[i]f caffeine were a newly synthesized drug, its manufacturer would almost certainly have great difficulty getting it licensed under current

---

[220] *See* Prothro, *supra* note 13, at 77; *see generally* 21 U.S.C. Ch. 9, Subch. V, Part A (2009).

[221] Prothro, *supra* note 13, at 77.

[222] International Food Information Council, Fact Sheet: Caffeine and Health, Aug. 2007, *available at* http://www.ific.org/publications/factsheets/caffeinefs.cfm.

[223] *See* Energy Fiend, *supra* note 33, *A Real Life Death by Caffeine*, http://www.energyfiend.com/2007/04/a-real-life-death-by-caffeine (April 2007) (last visited Oct. 1, 2009) (showing photo of No Doz box, displaying "200mg caffeine" content label); Vivarin Website, http://www.vivarin.com/images/infocenter/vivarin_front.gif (last visited Oct. 1, 2009) (showing photo of Vivarin box, disclosing "200mg caffeine" content label).

[FDA] regulations. If it were licensed, it would almost certainly be available only by prescription."[224]

However, caffeine is not a newly synthesized drug. With thousands of years of usage history behind it, caffeine remains a strong and legal presence in society. However, caffeine may not be in the clear since this light treatment of caffeine by the government opens caffeine product manufacturers to public nuisance lawsuits.

E. Public Nuisance Law: Is "Big Caffeine" the Next Target?

The tort of nuisance has emerged in recent years as one way to combat the safety problems posed by various products, despite the lack of a coherent nuisance doctrine for publicly-sold products. "There is perhaps no more impenetrable jungle in the entire law than that which surrounds the word 'nuisance.'"[225] Recently, "the tort of 'public nuisance' has emerged as a potentially useful tool utilized by states and municipalities looking to spread the economic cost of large-scale societal ills."[226] In addition, the boundaries of public nuisance law have been stretched by individuals who have brought a skyrocketing number of lawsuits against tobacco companies,[227] gun manufacturers,[228] lead paint companies,[229] fast food restaurants,[230] and automobile makers.[231] This trend,

---

[224] MICHAEL CASTLEMAN, THE NEW HEALING HERBS 148 (2d ed. 2001) (alteration in original) (internal quotation marks omitted).

[225] PROSSER & KEETON, THE LAW OF TORTS § 86 (W. Page Keeton ed., 5th ed. 2004).

[226] Donna L. Wilson & Marla H. Kanemitsu, *Public Nuisance: A New Battleground for Policyholders and Insurers*, RISK & INS., April 1, 2008, *available at* http://www.riskandinsurance.com/story.jsp?storyId=83382382.

[227] *See generally* George P. Smith, II, *Cigarette Smoking as a Public Health Hazard: Crafting Common Law and Legislative Strategies for Abatement*, 11 MICH. ST. U. J. MED. & L. 251 (2007).

[228] *See generally* Joseph W. Cleary, Comment, *Municipalities Versus Gun Manufacturers: Why Public Nuisance Claims Just Do Not Work*, 31 U. BALT. L. REV. 273 (2002).

[229] *See generally* John S. Gray & Richard O. Faulk, *Judges Impose Reality Check on Public Nuisance Litigation*, LEGAL BACKGROUNDER, July 27, 2007, at 1, *available at* www.wlf.org/upload/07-27-07faulk.pdf; Fredrick C. Schaefer & Christine Nykiel, *Lead Paint: Mass Tort Litigation and Public Nuisance Trends in America*, 74 DEF. COUNSEL J. 153 (2007).

[230] *See generally* Samuel J. Romero, Comment, *Obesity Liability: A Super-Sized Problem or a Small Fry in the Inevitable Development of Product Liability?*, 7 CHAP. L. REV. 239 (2004).

[231] *See generally* Randall S. Abate, *Automobile Emissions and Climate Change Impacts: Employing Public Nuisance Doctrine as Part of a "Global Warming Solution" in California*, 40 CONN. L. REV. 591 (2008).

coupled with rising dissatisfaction with the way caffeine is regulated under DSHEA, leaves manufacturers of caffeine-containing products in a potentially vulnerable position.[232]

The Restatement (Second) of Torts defines a "public nuisance" as "an unreasonable interference with a right common to the general public."[233] Under this theory, one may, on behalf of the public, bring suit to enjoin conduct that is causing the nuisance, or "to compel the party responsible to abate" it.[234]

It is conceptually difficult to characterize caffeine-containing products as presenting an unreasonable interference with a public right. However, recent years have seen a surge in the number of class action "consumer deception lawsuits . . . filed against food companies" similar to nuisance suits for producing similarly non-public "harms" such as obesity.[235] Many of these suits are "sponsored by public interest groups" looking to the framework of tobacco litigation for "inspiration."[236]

While most of these suits ultimately fail, advocacy groups continue to bring them, believing that "litigation increases public knowledge, forces companies to stop objectionable marketing practices, and drives up prices for the targeted items, which in turn reduces consumer demand for allegedly unhealthy choices."[237] Thus, public nuisance lawsuits are not necessarily brought in hopes of winning, but rather to "serve as an alternative or even a shortcut to legislation and regulation, advancing public health even in the absence of a win in court."[238] By altering the current regulatory approach to caffeine, Congress can quell many of the legitimate concerns surrounding excessive caffeine consumption. This would also serve to address the concerns of various advocacy groups, thus preventing the waste of judicial resources on ill-fated public nuisance claims.

---

[232] Posting of Timothy Sandefur to Freespace, http://sandefur.typepad.com/freespace/ (Aug. 9, 2008, 08:39).

[233] Restatement (Second) of Torts § 821B(1) (1979).

[234] Wilson & Kanemitsu, *supra* note 226 (discussing the fundamentals of public nuisance laws and the circumstances under which one may bring suit on behalf of the public).

[235] Sarah Taylor Roller et al., *Obesity, Food Marketing and Consumer Litigation: Threat or Opportunity?*, 61 FOOD & DRUG L.J. 419, 420, 428 (2006).

[236] *Id.* at 428.

[237] *Id.* at 429.

[238] *Id.*

III. RECOGNIZING THE ISSUE AND FINDING A SOLUTION

The growing concern with excessive caffeine consumption, particularly among young people, requires a delicately balanced solution. The link between caffeine and the harms that excessive consumption can cause is not as strong as the link between smoking and cancer, or alcoholism and liver damage. However, both tobacco usage and alcoholism were pervasive in U.S. society for decades before the government openly acknowledged their problematic health effects.

In contrast, the government's concerns over caffeine date back decades. In the 1920s, when early advertisements for soft drinks focused on the appeal of caffeine as a stimulant, the government questioned the use of caffeine as an additive in soft drinks.[239] However, "[t]he objections . . . were countered by the industry."[240] In 1981, the FDA considered removing caffeine's GRAS status.[241] While manufacturers claimed the additive was a flavor factor, research now shows that "[t]he majority of people who drink colas can't tell whether [it] contains caffeine or not."[242] The incentive to add addictive caffeine to soft drinks is clear. Manufacturers' addition of "a mildly addictive, mood-altering drug . . . surely accounts for the fact that people drink far more sodas with caffeine than without."[243]

This scenario is not a novel one in our history. The 1990s brought many new revelations of the "disingenuous stance of [tobacco] industry executives about the addictive properties of nicotine" and other efforts to conceal and misrepresent tobacco-related health concerns.[244] Smokers around the country believed that tobacco companies systematically and deliberately concealed the risk of cigarette use "but also had purposefully designed their product to foster

---

[239] Press Release, Johns Hopkins Medicine, Caffeine In Colas: "The Real Thing" Isn't the Taste (Aug. 14, 2000), *available at* www.hopkinsmedicine.org /press/2000/AUGUST/000814.HTM [hereinafter The Real Thing] (quoting researcher, Roland Griffiths, Ph.D.).

[240] *Id.*

[241] *Id.*

[242] *See id.*

[243] *Id.* (internal quotation marks omitted) (quoting researcher Roland Griffiths, Ph.D.) "About 70 percent of all soft drinks in this country contain caffeine . . . [t]he caffeine-free versions of Coca-Cola Classic and Pepsi, the two most popular soft drinks, make up only 5 percent of sales of those sodas." *Id.*

[244] Robert L. Rabin, *The Third Wave of Tobacco Tort Litigation, in* REGULATING TOBACCO 176, 184 (Robert L. Rabin & Stephen D. Sugarman eds., 2001).

addiction."[245] As one researcher has stated, "[t]he marketing parallels between nicotine and caffeine are pretty stunning."[246]

The last few decades have brought new information on the dangers of caffeine as an additive, as well as a slew of new, highly caffeinated products. Yet the FDA currently lacks a "coherent policy" on how to regulate these products.[247] One former FDA official acknowledged the agency's struggle to keep up, stating that "[t]he market is moving faster than we can sit down and think things through."[248] This is even more problematic given that current caffeine consumption trends illustrate that there is a developing abuse problem. Therefore, some action is needed.

A. Step One: Proposed Changes to the Existing Law

The biggest shortcoming of the current regulatory scheme is inconsistency. In order to change this, Congress should make several changes to the current statutory scheme surrounding caffeine.

First, the FDA, instead of the manufacturers, should bear the burden of conducting safety tests for all products containing over 300mg of caffeine. This would create a disincentive for manufacturers of energy drinks to continue to compete on the basis of alarmingly high caffeine contents. Further, with the threshold set at 300mg, the production of many energy drinks and caffeine pills, (which are currently regulated as drugs and thus already subject to separate testing requirements) would not be interfered with.

Second, the current standard that the FDA must meet in order to pull an item off the market must be better defined, if not altogether scrapped in favor of a new, lower threshold. The term "significant or unreasonable risk of illness or injury" needs to be clarified to give the FDA an unambiguous sense of

---

[245] *See* Donald G. Gifford, *The Peculiar Challenges Posed by Latent Diseases Resulting from Mass Products*, 64 MD. L. REV. 613, 624 (2005); *see also* United States Final Proposed Findings of Fact at 15, United States v. Philip Morris USA Inc., 477 F. Supp. 2d 191 (D.D.C. 2007) (No. 99-CV-02496 (GK)). ("Defendants purposefully designed and sold products that delivered a pharmacologically effective dose of nicotine in order to create and sustain nicotine addiction in smokers.").

[246] The Real Thing, *supra* note 239 (quoting Roland Griffiths, Ph.D.).

[247] Ilene Ringel Heller, *Functional Foods: Regulatory and Marketing Developments*, 56 FOOD & DRUG L.J. 197, 197 (2001).

[248] *See id.* at 198 (internal quotation marks omitted) (quoting *FDA Labeling Policy "Established Through Enforcement": Campbell*, FOOD REG. WKLY., Jan. 4, 1999, at 4).

its own ability to conduct investigations earlier on in the process.

Finally, in addition to requiring manufacturers of dietary supplements to verify the ingredients they are adding to their products, the FDA should also be able to require these manufacturers to produce relevant research on the "dangerous quantity" issue. To get a more accurate "big picture," the manufacturers should provide these statistics as they apply to the particular consumer base that the manufacturer targets. For example, if Manufacturer X's marketing and sales data show that it specifically targets twelve to twenty-four year olds, Manufacturer X would be required to provide relevant statistical research on what is likely to be a "dangerous quantity" when consumed by the average consumer fitting the profile for that particular age segment. This would prevent manufacturers from labeling their product lines based on generalized research, while marketing to younger segments of the population with lower caffeine toxicity thresholds. Such an approach would focus attention on the importance of preventing abuse by younger Americans.

B. Step Two: Awareness Through Soft Paternalism

In addition to encompassing legal reform, an appropriate response would include a soft paternalist "awareness campaign" that strikes an appropriate middle ground between unwarranted, premature government intervention, and governmental ignorance of a pending caffeine abuse problem.

Paternalism generally refers to "the interference of a state or an individual with another person, against their will, and justified by a claim that the person interfered with will be better off or protected from harm."[249] Examples of legal paternalism include "anti-drug legislation, the compulsory wearing of seatbelts, and in medical contexts by the withholding of relevant information concerning a patient's condition by physicians."[250] Within this legal concept are varying types and degrees of paternalism. Soft paternalists believe "that the only conditions under which state paternalism

---

[249] Gerald Dworkin, *Paternalism, in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY, (Edward N. Zalta ed., 2008), *available at* http://plato.stanford.edu/archives/fall2008/entries/paternalism/.

[250] *Id.*

is justified is when it is necessary to determine whether the person being interfered with is acting voluntarily and knowledgably."[251] Meanwhile, "hard paternalists" believe in total bans or mandates, irrespective of the actors' mental states.[252] To illustrate the distinction, soft paternalists support seatbelt campaigns, while hard paternalists support seatbelt laws.

Soft paternalism presents a more feasible and appropriate option than a total caffeine ban. As one commenter has noted, "consumers [should] be permitted to make their own judgments about risks on the basis of complete and accurate information about the hazards involved . . . [and] that decision [should not] be taken out of their hands by banning a food product."[253] While a hard paternalist may argue in favor of a ban, asserting that people appear incapable of making the rational choice to consume caffeine in moderation and preserve their own health, this approach is very drastic and impinges upon Americans' rights to not only make their own choices, but to engage in behavior, which in moderation, does not usually cause harm. In that sense, a hard paternalist approach would be far too overbroad. A soft paternalist approach may yield more favorable results, particularly since the problem of caffeine over-consumption is not one based solely on irrationality; rather, it is often based on a lack of general information.

For these reasons, any approach to caffeine consumption concerns must acknowledge caffeine's various health benefits and dangers, and seek to present information in a way that enables the public to make the same distinction. One such option would be a government-funded "caffeine awareness campaign," intended to increase general awareness of the benefits of moderate caffeine consumption and dangers of excessive caffeine consumption. The focus of this campaign would not be to discourage caffeine use altogether, but rather, to help make consistent recommendations with respect to defining "moderation." To do this, the government would strive to educate the public on the meaning of "moderation" as being approximately 200mg, which is consistent with the FDA's

---

[251] *Id.*

[252] *Id.*

[253] Prothro, *supra* note 13, at 86 (quoting Peter B. Hutt, *The Basis and Purpose of Government Regulation of Adulteration and Misbranding of Food*, 33 FOOD DRUG COSM. L. J. 505, 537 (1978)).

current recommended daily consumption for the average adult.[254]

Such a campaign would need to be simplistic and casual in order to be effective—not a scare tactic used to attack the caffeine industry. It could include posters in subway stations, lectures in high-school health classes, and flyers at doctors' offices and gyms. These posters would directly address those who are at risk: people who find themselves experiencing typical withdrawal symptoms, who feel they may be unwillingly becoming dependent on caffeine, or those who are looking for healthier alternatives, such as decaf coffee or tea. These groups could easily be targeted in a proactive way, so as to not impose a "psychic tax" on those who are already making rational choices by moderating their consumption. Peter Barton Hutt has emphasized the importance of striking this balance:

> If health promotion . . . programs depend solely, or even primarily, on personal self-sacrifice and abjuration, they are doomed to failure. The prevalence of alcoholism in this country is a monument to the futility of such efforts. It would be an equally grave error for the Federal government to attempt to prohibit even some of the small joys and pleasures of eating. The rise and fall of Prohibition . . . attest[s] to that. To have any chance for success, programs of health promotion . . . must avoid attempts to reduce individual freedom of choice and action, and concentrate instead upon providing attractive alternatives that are voluntarily and freely chosen or, indeed, that require no change in lifestyle whatever.[255]

While it seems unlikely, Gwendolyn Prothro's scheme for FDA mandated disclosure of caffeine content would certainly help bring consistency to the current framework, while supplementing a soft paternalist awareness campaign.[256] This scheme would help provide consumers with the information they need to make well-informed decisions, without putting the government in a non-neutral position, since the requirements would apply to all caffeine containing products, including pills and energy drinks alike.

Ideally, this campaign would be very similar to the recent "healthy eating" campaign launched by New York City to help combat widespread obesity among both adults and

---

[254] FDA AND YOU, *supra* note 11.

[255] Peter Barton Hutt, *Regulatory Implementation of Dietary Recommendations*, 36 FOOD & DRUG L.J. 66, 69 (1981).

[256] *See generally* Prothro, *supra* note 13.

children. This initiative came in response to alarming statistics indicating that New York City adults were rapidly gaining unhealthy amounts of weight.[257] This campaign, which became effective in mid-2008,[258] requires certain restaurants to prominently post calorie contents of foods and beverages,[259] and seems to be at least somewhat effective in educating those who wish to increase their awareness.[260] While it has been challenged in court on various grounds, including under the First Amendment, the regulation has been upheld,[261] and "[l]egislation similar to New York City's is under way in [fourteen] states where obesity rates have recently surged—Arizona, California, Connecticut, Hawaii, Illinois, Maine, Massachusetts, Michigan, New Jersey, New Mexico, New York, Pennsylvania, Tennessee and Vermont . . . [and n]utrition labeling legislation has also been introduced in Chicago, Philadelphia and Washington."[262] What is important to note is that those who make choices regardless of calorie content are relatively unaffected by this campaign. For example, a consumer who previously ordered a double bacon cheeseburger on a daily basis was likely aware, even prior to this regulation, that his choice was a relatively unhealthy one. For someone like this, calorie postings may have a minimal impact. They are just stating the obvious, in numerical terms. However, calorie postings may have a different impact on someone who makes a conscious effort to choose healthier alternatives when eating out. This person may believe that the grilled chicken Caesar salad is a healthier option relative to the cheeseburger.

---

[257] Gretchen Van Wye et al., *Obesity and Diabetes in New York City*, *2002 and 2004*. 5 PREVENTING CHRONIC DISEASE (April 2008), http://www.cdc.gov/pcd/issues/2008/apr/07_0053.htm ("The rapid increase in obesity and diabetes in New York City [that] suggests the severity of these twin epidemics and the importance of collecting and analyzing local data for local programming and policy making.").

[258] This regulation applies to any New York City chain restaurant that has 15 or more outlets nationwide. NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, THE REQUIREMENTS TO POST CALORIE COUNTS ON MENUS IN NEW YORK CITY FOOD SERVICE ESTABLISHMENTS: HOW TO COMPLY 2 (2008), http://www.nyc.gov/html/doh/downloads/pdf/cdp/calorie_compliance_guide.pdf.

[259] *Id.*

[260] *Id.*

[261] *See generally* N.Y. State Rest. Ass'n. v. N.Y. City Bd. of Health, 556 F.3d 114 (2d. Cir. 2009) (holding that city law was not preempted by the federal statutory scheme regulating labeling and branding of food; that rational basis was the appropriate standard for determining whether the city law violated the First Amendment's protection of commercial speech; and that the law was reasonably related to its goal of reducing obesity).

[262] Associated Press, *Judge Strikes Down NYC Calorie-Posting Rule*, MSNBC.COM, Sept. 11, 2007, http://www.msnbc.msn.com/id/20725624/.

However, this person may be shocked to learn of the high caloric content of some fast food salads, often a result of high-calorie, high-fat dressings, croutons, and cheeses. For this consumer, calorie postings may serve their intended purpose.

Similarly, caffeine content postings would likely have little effect on "intensity seekers." One who regularly downs several Red Bulls in one sitting will probably continue to do so. However, the young man who has recently been diagnosed with an otherwise harmless heart murmur may be shocked to learn that his daily pick-me-up contains twice as much caffeine as he thought it did and could cause him future problems. Or perhaps he realized that a serving size of his favorite energy drink was only one half of a can. Next time, he may opt for a "half-caf"[263] instead of a regular or drink only half of the can at a time. In sum, while the campaign may not affect everyone's choices, it will certainly help guide those who are not consciously making unhealthy choices.

New York's initiative has proven so promising that the city has taken the idea further and plans to use it to educate consumers on salt intake in order to combat other social ills such as heart attacks and strokes.[264] This is all part of the broader goal of helping New Yorkers make healthier choices. In addition to educating the public about daily intakes of calories and salt, the government is also actively recommending limits to allow the public to put its newly gained knowledge into perspective. For example, the city has also started a three-month "healthy eating campaign," which consists of posters in subways recommending that most adults limit their daily caloric intake to 2,000 calories.[265] These posters appeared in subway cars and provided calorie counts for several popular, generic menu items, like muffins and burritos.[266]

The popularity of this scheme indicates that a similar campaign with respect to caffeine may also be effective. By requiring manufacturers of caffeine-containing products to post

---

[263] A half decaffeinated, half caffeinated coffee.

[264] *See* New York City Dep't of Health and Mental Hygiene, NYC Starts a Nationwide Initiative to Cut the Salt in Restaurants and Processed Food, http://www.nyc.gov/html/doh/html/cardio/cardio-salt-initiative.shtml ("Mayor Bloomberg and the New York City Health Department have launched a nationwide effort to prevent heart attacks and strokes by reducing the salt levels in processed and restaurant foods.") (last visited Oct. 16, 2009).

[265] *NYC Calorie-Counting Ads Hit Subway*, USA TODAY, Oct. 7, 2008.

[266] *Id.* (calorie content of "470 for a giant apple bran muffin or 1,170 for a chicken burrito with toppings").

caffeine content as part of a broader awareness-boosting campaign, consumers would gain a better sense of their overall caffeine consumption. The goals of increasing consumer awareness could easily be reached without placing high costs on manufacturers of caffeine-containing products.

What makes this scheme particularly attractive is that variations of it have already been acknowledged by the FDA as being appropriate. In 1981, when the FDA proposed deleting caffeine from the GRAS list, the Commissioner of Food and Drugs at the time, in response to various comments on the proposal, announced the FDA's intention to begin a campaign "to provide the public with information concerning the possible adverse effects of caffeine."[267]

Such attempts at increasing consumer awareness have been made in other contexts as well. Most notable is the effect of the Surgeon General's warning on cigarette packages, which increased risk awareness by up to 300 percent.[268] Other state and local governments have experimented with posters designed to educate the public about alcohol, finding similar results.[269]

In particular, such visual reminders could make a significant impact on adolescents' awareness of caffeine's risks. Since this market is especially vulnerable, it is important to strike a delicate balance when creating campaign materials. Some research indicates that "as they age, adolescents depend increasingly on advertising as an information source, and there is justifiable concern about the marketing appeals . . . to which they are exposed."[270]

IV. CONCLUSION

Despite the ever-increasing prevalence of coffeehouses and caffeine's generally accepted role in contemporary society,

---

[267] Caffeine: Deletion of the GRAS Status, 45 Fed. Reg. 69,817, 69,834 (Oct. 21, 1980) (to be codified at 21 C.F.R. pts. 180, 182).

[268] *See generally* D. Hammond et al., *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings From the International Tobacco Control (ITC) Four Country Survey*, 15 (Supp. III) TOBACCO CONTROL iii19-iii25 (2006).

[269] *See generally* Andrea M. Fenaughty & David P. MacKinnon, *Immediate Effects of the Arizona Alcohol Warning Poster*, 12 J. PUB. POL'Y & MARKETING 69, 69-77 (1993).

[270] *See generally* Richard J. Fox et al., *Adolescents' Attention to Beer and Cigarette Print Ads and Associated Product Warnings*, J. ADVERTISING, Fall 1998, at 57.

caffeine has always been, and will continue to be, a "drug." The issues raised by recent caffeine consumption trends require a delicately balanced approach. While caffeine may not raise the same sorts of health issues as alcohol or tobacco, usage patterns among young people nonetheless echo some of the same dependency concerns. Perhaps the biggest impediment to consumer awareness is the current inconsistency of the statutory framework surrounding caffeine, which was exacerbated by the 1994 passage of DSHEA. With small, balanced steps, the government can help the average consumer define "moderation" and prevent currently alarming trends from turning into a real "drug" problem in years to come.

Nausheen Rokerya[†]

[†] J.D. Candidate, Brooklyn Law School, 2010; B.S., Cornell University, 2007. The author thanks her husband, parents, and siblings for their unwavering support and understanding throughout her law school studies. The author also thanks the members of the *Brooklyn Law Review* for their time and assistance.